

EXHIBIT C

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: F.B. Rice & Co. 139 Rathdowne Street CARLTON VIC 3053			Date of mailing <i>(day/month/year)</i> 25 MAY 2005
Applicant's or agent's file reference 503310		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/AU2005/000467	International filing date <i>(day/month/year)</i> 31 March 2005	Priority date <i>(day/month/year)</i> 31 March 2004	
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ C12N 15/29, 15/52			
Applicant COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al			

1. This opinion contains indications relating to the following items:

- ☒ **Box No. I** Basis of the opinion
- ☐ **Box No. II** Priority
- ☒ **Box No. III** Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ **Box No. IV** Lack of unity of invention
- ☒ **Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ **Box No. VI** Certain documents cited
- ☐ **Box No. VII** Certain defects in the international application
- ☐ **Box No. VIII** Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer PHILIPPA WYRDEMAN Telephone No. (02) 6283 2554
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2005/000467

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos: 28-44 and 46-60 in full, 1-27, 45 and 61-84 in part

because:

- ☐ the said international application, or the said claim Nos.
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for said claims Nos. 28-44 and 46-60 in full, 1-27, 45 and 61-84 in part

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. The fundamental test for unity of invention is specified in Rule 13.2 of the Regulations under the PCT.

"Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, make over the prior art."

The problem addressed by the application is a need for the identification and characterization of genes involved in the fibre initiation in fibre producing plants such as cotton. The solution provided by the claims resides in the identification and partial characterisation of 16 such genes that code for the proteins defined by Sequence IDs 1-16 (see Key to Sequence Listing at page 17 of the description) and methods of using these sequences to alter fibre development. The general concept underlying the application appears to reside in the polypeptides and nucleotides encoding proteins that play some role in fibre initiation or elongation. The solution provided by the claims is directed to polypeptides (and the genes encoding these) that regulate fibre initiation and/or elongation and the use of these to alter fibre development. However, these concepts are not a new concept as can be seen, for example, from the following documents:

Jl, S-J. et al (2003) "Isolation and analysis of genes preferentially expressed during early cotton fiber development by subtractive PCR and cDNA array" *Nucleic Acids Research*, 31(10): 2534-43.

SUO, J. et al (2003) "Identification of *GhMYB109* encoding a R2R3 MYB transcription factor that expressed specifically in fiber initials and elongating fibers of cotton (*Gossypium hirsutum* L.)" *Biochimica et Biophysica Acta* 1630: 25-34.

US 5932713 A (Kasukabe et al) 3 August 1999

Continued on supplemental sheet.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts
- ☒ the parts relating to claims Nos. 1-27, 45 and 61-84 in part, in so far as they relate to GhHD1 (seq ID no. 1 and 17)

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Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 1-27, 45 and 61-84	YES
	Claims none	NO
Inventive step (IS)	Claims 1-27, 45 and 61-84	YES
	Claims none	NO
Industrial applicability (IA)	Claims 1-27, 45 and 61-84	YES
	Claims	NO

2. Citations and explanations:

The following citations from the International Search report are referred to:

- D1. US 5932713 A (Kasukabe et al) 3 August 1999
- D2. SUO, J. et al (2003) "Identification of *GhMYB109* encoding a R2R3 MYB transcription factor that expressed specifically in fiber initials and elongating fibers of cotton (*Gossypium hirsutum* L.)" *Biochima et Biophysica Acta* 1630: 25-34.
- D3. JI, S-J. et al (2003) "Isolation and analysis of genes preferentially expressed during early cotton fiber development by subtractive PCR and cDNA array" *Nucleic Acids Research*, 31(10): 2534-43.

Novelty and Inventive Step:

D1- D3 all direct to polypeptides (and the genes encoding these) that regulate fibre initiation and/or elongation and the use of these to alter fibre development. None of these documents outline the polypeptide GhHD1 as claimed nor any polypeptides with similar function that are sufficiently homologous to GhHD1 to provide basis for any inventive step objection. Thus, claims 1-27, 45 and 61-84, in so far as they are limited to GhHD1 are considered both novel and inventive.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box IV

These documents disclose polypeptides and their genes that are involved in the regulation of fibre initiation and/or elongation and/or the use of such genes to alter fibre development. The protein groups do share the feature of being from the plant species *Gossypium hirsutum*. However the species of origin can only constitute a special technical feature if the species or origin makes a contribution over the prior art. There is nothing in the application to indicate that isolation of peptides from cotton is inventive. It was known that fibre regulatory genes would be present in cotton and how to go about identifying them. Since there is no obvious special technical feature, it is appropriate to use the Markush approach to analyse the situation.

The application of the test for Markush claims gives the following result:

- (A) the common property is regulation of fibre initiation and/or elongation in plants.
- (B) (1) no common structure is evident as the structures of the polypeptides are not revealed
- (B) (2) there is no single recognised class of compounds embracing all the polypeptides, as the polypeptides appear to belong to different classes. Each of the 16 polypeptides has a different function (where the polypeptide has been characterised at all – note GhFU1 and GhFU2 that are considered unknown and thus have no identified function). It is contrary to normal classification to group together such different polypeptides.

The species of origin of the polypeptides does not provide a legitimate classification as proteins are primarily classified by their activity not their origin. Thus the polypeptides can be grouped into 16 classes based on their activities. These classes of proteins represent 16 different inventions.

Furthermore, not all inventions can be searched without significant additional effort.

The applicant has chosen not to pay additional fees and thus this International Search Authority has restricted the search and opinion to the molecule GhHD1 (Sequence ID no. 1).